K061311

SEP 22 2006

510(k) SUMMARY

Allogran-R®

Applicant

Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person

Mr Simon Fitzer
Tel: +44 (0) 1782 338580
Fax +44 (0) 1782 338599
Email: sf@biocomposites.com

Classification Name: Filler, bone void, calcium compound

Common/Usual Name: Filler, bone void, calcium compound

Trade/Proprietary Name Allogran-R®

Product Code MVQ

Legally Marketed Predicate Devices

	Trade Name	Manufacturer	510(k) No
1	Vitoss Scaffold	Orthovita	K032409
2	βGran	Orthos (UK) Ltd	K041616

Device Description

Allogran-R® is a bioabsorbable device manufactured from calcium salts and may be supplied in the form of granules or other preformed shapes.

Intended Use / Indications

Allogran-R® is a resorbable implant intended to fill bony voids or gaps that are not intrinsic to the stability of the bony structure (e.g., the extremities, spine or pelvis) and may be combined with saline or blood. Defects may be due to trauma or surgery.

Summary of Technology

Allogran-R® has the same technological characteristics as the predicate devices and any differences do not raise concerns concerning safety and effectiveness.

Non Clinical Testing

Test data supplied demonstrates that the Allogran-R® is substantially equivalent to the predicate devices and any differences do not raise concerns concerning safety and effectiveness.

Substantial Equivalence

Documentation provided demonstrates that Allogran-R® is substantially equivalent to the legally marketed predicate devices in basic features and intended uses. No new concerns have been identified regarding safety and effectiveness of Allogran-R®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2006

Biocomposites Ltd.
% Mr. Simon Fitzer
Quality and Regulatory Affairs Manager
Keele Science Park
Keele Staffordshire
United Kingdom ST5 5NL

Re: K061311
Trade Name: Allogran-R®
Regulation Number: 21 CFR 888.3045
Regulation Name: Filler, Bone Void, Calcium Compound
Regulatory Class: Class II
Product Code: MQV
Dated: September 6, 2006
Received: September 8, 2006

Dear Mr. Fitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061311

Device Name: Allogran-R®

Indications For Use:

Allogran-R® is a resorbable implant intended to fill bony voids or gaps that are not intrinsic to the stability of the bony structure (e.g., the extremities, spine or pelvis) and may be combined with saline or blood. Defects may be due to trauma or surgery.

Prescription Use ✓ OR Over-The-Counter use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological D

510(k) Number K061311